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**APPENDIX A**

**VOLUNTARY  
INDUSTRY SANITATION  
GUIDELINES FOR  
FOOD DISTRIBUTION  
CENTERS AND  
WAREHOUSES**

**1974**



*Sponsored by:*

**ASSOCIATION OF INSTITUTIONAL DISTRIBUTORS  
COOPERATIVE FOOD DISTRIBUTORS OF AMERICA  
GROCERY MANUFACTURERS OF AMERICA  
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INTERNATIONAL FOODSERVICE MANUFACTURERS ASSOCIATION  
NATIONAL-AMERICAN WHOLESALE GROCERS' ASSOCIATION  
NATIONAL ASSOCIATION OF FOOD CHAINS**

*In cooperation with the*  
**U. S. FOOD AND DRUG ADMINISTRATION**

## I. FOREWORD

These guidelines were prepared for receiving, handling, storage, and shipping of food and food products contained in retail and/or shipping containers at food distribution centers and food warehouse establishments, referred to as "food warehouses" throughout these guidelines. The term "food(s)" in these guidelines means foods and food products which are contained in retail and/or shipping containers, but includes items such as fresh produce received unpackaged or in partially open packages, which are subject to various specific additional portions of the guidelines.

The purpose of these guidelines is to promote receiving, handling, storage, and shipping of food and related items at such establishments in a manner that will assure the continued delivery of safe, sanitary, and wholesome foods to consumers.

It is further intended that conscientious adherence to the letter and spirit of these guidelines will not only minimize the chance of noncompliance with applicable governmental requirements for food sanitation, but will improve and maintain the overall effectiveness and quality of the practices by which foods are brought to the American consumer.

In this context, it is essential that management, including those directly responsible for any food warehousing activity, make provision for persons employed in a food handling capacity to receive the degree of training, emphasis, and support commensurate with their job responsibilities and with ensuring the effective implementation of the provisions of this document.

These guidelines, of necessity, are neither exclusive nor all inclusive; they are, however, intended to assist management and food warehouse operators in developing and maintaining facilities, methods, practices, and controls for

the receiving, handling, storage, and shipping of foods at the food warehouse establishment in a manner that protects the public health.

They are designed to deal with exposed or otherwise uncovered foods only to the extent that such foods are exposed or uncovered during receiving, handling, storage, and shipping in the food warehouse establishment.

They are not designed to cover food manufacturing, processing, or packaging areas and related equipment, practices, and procedures which are subject to regulations and/or guidelines specifically developed for those types of operations.

If food warehousing and food manufacturing, processing, or packaging operations are maintained in the same establishment, neither type of operation should interfere with the compliance with any good sanitation practices, guidelines, or regulations applicable to the other type or types of operations.

## II. BUILDINGS AND GROUNDS

### A. *Maintain Grounds Around Warehouses in a Sanitary Manner :*

- Maintain the grounds around food warehouse buildings under the control of the operator in a well-drained condition, and free from conditions likely to lead to contamination of foods in the food warehouse, leaving the food warehouse, or being delivered to the food warehouse.

- Keep grounds clean and free of discarded equipment, lumber, litter, waste, refuse, and uncut weeds or grasses within the immediate vicinity of the food warehouse which may provide breeding places or harborage for rodents, insects and other pests.

- Locate outside waste disposal containers on properly drained areas, clean them as needed, and keep them covered between use.

- Maintain and surface driveways, truck aprons, and rail sidings at receiving and shipping areas and parking areas to facilitate good drainage and to minimize dust and dirt being blown or tracked into the food warehouse. Maintain them in a clean, well-drained condition.

- If the food warehouse buildings are closely bordered by grounds not under the operator's control, exercise special care in the food warehouse, by inspection, extermination, or other means, to exclude and control pests, dirt, and other potential contaminants originating from such non-controlled grounds.

*B. Maintain and Operate Food Warehouse Buildings and Structures in a Sanitary Manner:*

- Provide floors and interior walls which are adequately cleanable and keep them clean and in good repair.

- Suspend fixtures, ducts, and pipes which are over working areas so as to prevent drip or condensate from contaminating food or food packages.

- Maintain adequate separation by location or other effective means for those operations which may cause contamination of foods with undesirable chemicals, filth, or other extraneous material.

- Provide adequate lighting to areas where food is received, stored, held or assembled for delivery, in order to facilitate handling, processing, and examination of merchandise and to permit adequate inspection, clean-up, and repair of the buildings and their structures.

- Provide adequate lighting in hand washing areas, dressing and locker rooms (if present), and toilet rooms.

- Employ appropriate special efforts to maintain sanitation whenever necessitated by unique features of structure or design.

- In a food warehouse utilizing light bulbs, light fixtures, skylights or other glass over exposed food, such as produce items in mesh bags, etc., use safety type bulbs or shielded fixtures to prevent food contamination in case of breakage.

### III. FIXTURES AND EQUIPMENT

- Provide food warehouse equipment which is suitable as used and maintained, and is of design, material, and workmanship which permits it to be adequately cleaned and properly maintained by the methods used at the establishment.

- Use and maintain the equipment so as to prevent the adulteration of foods with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

- Install and maintain equipment in a manner which will facilitate its cleaning and the cleaning of adjacent spaces.

### IV. SANITARY FACILITIES

Provide the food warehouse with adequate sanitary facilities and accommodations:

#### A. *Water Supply:*

- From an adequate source, provide a water supply which is sufficient for the food warehouse operations.

#### B. *Sewage:*

- Dispose of sewage into an adequate sewerage system or through other appropriate means.

#### C. *Plumbing:*

- Install and maintain plumbing of adequate capacity and design and in accordance with applicable governmental sanitation requirements, if any, so as to provide sufficient

quantities of water to required locations throughout the food warehouse, and to properly convey sewage and liquid disposable waste from the food warehouse.

**D. Toilet Facilities:**

- Provide toilet facilities which are adequate, kept in good repair, conveniently located, well-ventilated, and in compliance with applicable governmental sanitation requirements, if any.

- Provide them with self-closing doors and with walls, ceilings, and floors which are tight fitting and of a material which can be easily cleaned and kept in good repair; and maintain them in a clean condition.

- Furnish toilet rooms with toilet tissue, and post signs instructing employees to wash their hands with soap or detergent before returning to work.

- If toilet rooms are located near areas in the food warehouse where exposed foods, such as produce items in mesh bags, might be subjected to airborne contamination, provide them with self-closing doors which do not open directly into such areas.

**E. Hand Washing Facilities:**

- Provide adequate hand washing facilities in the toilet rooms or in places convenient to the toilet rooms for hand washing after use of the toilets.

- Furnish such facilities with hot and cold running water, hand-cleansing soaps or detergents, sanitary towels, or other suitable drying devices.

- Provide adequate receptacles, with covers, for disposal of hand-drying articles or waste material.

- Maintain the washing facilities and the surrounding areas in a clean condition.

#### *F. Dressing and Locker Areas:*

- If dressing and locker areas are present, provide them with adequate ventilation and lighting, and maintain them in a clean and orderly condition.
- If lockers are present, provide them with sufficient ventilation to keep them dry for the retardation of mold and odors and maintain them in a clean condition, free from trash, food scraps, or litter which serve as insect or rodent attractants. Keep the tops of such lockers clean, and do not use them as surfaces for the storage of materials.

#### *G. Eating Areas:*

- If there are eating areas in the food warehouse, enclose them adequately or locate them in areas away from operations. Provide adequate space, light, and ventilation in such areas. Clean eating areas regularly, and provide them with a sufficient number of covered receptacles for disposal of meal trash. Clean such trash receptacles regularly and do not permit them to become insect or rodent attractants.
- Clean and inspect vending machines and surrounding areas at regular and frequent intervals to detect and correct conditions of insanitation which may exist in or around such machines.
- If drinking fountains are provided, locate them conveniently and clean them regularly.

### **V. SANITARY OPERATIONS**

#### *A. Keep Buildings and Equipment Sanitary:*

- Maintain buildings, fixtures, equipment, and other physical facilities of the food warehouse in good repair and in a sanitary condition.
- Conduct cleaning operations in such a manner as to minimize the danger of contamination. For cleaning and



sanitizing procedures, utilize detergents, sanitizers and other supplies which are safe and effective for their intended uses.

- Exclusive of packaged products held for distribution, store and use in the food warehouse only such toxic materials as are required for necessary activities, such as for maintaining sanitary and pest free conditions, for use in laboratory testing procedures, or for food warehouse and equipment maintenance and operation. Identify and use such products only in such manner and under such conditions as will be safe for the intended use.

- Use pesticides only under such precautions and restrictions as will prevent the contamination of food and food packaging materials.

#### **B. Rubbish:**

- Convey, store, and dispose of rubbish in a manner which will minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of warehoused food, food containers, ground surfaces, and water supplies.

#### **C. Pest Control Programs:**

- Establish and maintain positive control programs designed to exclude and eliminate pests from the food warehouse and to deny them harborage, in order to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects).

- Keep trained security dogs out of actual storage areas to avoid excreta contamination of foods stored at floor level. Keep cats out of the food warehouse.

- Implement these programs as an integral part of the construction, maintenance, operational, and personnel programs described elsewhere in the guidelines.

## VI. PROCEDURES AND CONTROLS

Conduct operations in the receiving, inspecting, transporting, handling, segregating, recouping, and storing of foods in accordance with appropriate sanitation principles. Implement overall sanitation under the supervision of an individual assigned responsibility for this function.

Take reasonable precautions, including the following, to assure that food warehouse procedures do not contribute to contamination of foods by harmful chemicals, objectionable odors, or other objectionable materials.

### *A. Incoming Product Shipments:*

The integrity of the food warehouse sanitation program requires that the materials, including foods and their packaging, which are received into the warehouse do not expose the food warehouse to contamination by reason of infestation by insects, birds, rodents, or other vermin, or by introduction of filth or other contaminants. It is often useful, when practicable, to work with suppliers and shippers in advance to establish guidelines for acceptance, rejection, and where appropriate, reconditioning of particular product, taking into consideration factors such as the nature, method of shipment, and ownership of the product, in order to facilitate the effective implementation of these programs.

1. Within a reasonable time after the arrival of a car or truck, and before product is unloaded, the product should be inspected to the extent permitted by the loading of the vehicle for evidence of damage or of insect or rodent infestation, objectionable odor, or other form of contamination.

Where an adequate inspection has not been possible prior to unloading, further inspect such product during and immediately after unloading.

2. If damaged product has been accepted, keep it separate from other product, and recondition or otherwise handle it as necessary in a manner which will not expose foods or the food warehouse to contamination or infestation.

3. If the inspection reveals evidence of infestation or contamination:

- Determine whether the condition is only "suspect," or is superficial (such as surface infestation of flying insects which may be on, but have not penetrated, soiled, or compromised the integrity of the packaging) and might be fully correctable by fumigation or other means.

- In each such case, remove the product from the food warehouse area, utilizing the vehicle in which it arrived, if feasible, after closing and sealing it.

- In case of contamination, if rejection is appropriate (based on the origin and ownership of the product), promptly notify the carrier and shipper of the time, place, and circumstances of the rejection.

- After removal from the food warehouse because of suspect and/or superficial conditions, concentrated efforts can be made to further evaluate the actual condition of the product, and to recondition it, when possible.

4. Give special attention to product which has previously been rejected, or has otherwise been removed from the food warehouse because of suspect and/or superficial conditions, when it is subsequently received again, to assure that the product and packaging are fully acceptable on reinspection.

5. In the event of serious question, or of failure to agree with the shipper or carrier, as appropriate, as to condition or reconditioning, consider requesting evaluation of the suspect or rejected product by appropriate federal, state, or local authorities.

**B. Store Product Properly:**

- Place foods received into the food warehouse for handling or storage in a manner which will facilitate cleaning and the implementation of insect, rodent, and other sanitary controls and will maintain product wholesomeness.

**C. Proper Stock Rotation:**

- Adopt and implement effective procedures to provide stock rotation appropriate to the particular food.

**D. Contaminated or Damaged Foods:**

- Unless promptly and adequately repaired or corrected at or near the point of detection, promptly separate foods which are identified as being damaged or are otherwise suspect from other foods for further inspection, sorting, and disposition.

- Promptly destroy or remove from the food warehouse product determined to present a hazard of contamination to foods in the food warehouse.

**E. Hazardous Non-Food Products:**

- Handle and store non-food products which present hazards of contamination to foods stored in the same food warehouse by reason of undesirable odors, toxicity of contents, or otherwise, in a manner which will keep them from contaminating the foods.

- Take special measures to safeguard from damage and infestation those foods which are particularly susceptible to such risks.

**F. Avoid Damage to Packaging:**

- Exercise care in moving, handling and storing product to avoid damage to packaging which would affect the contents of food packages, would cause spillage, or would

otherwise contribute to the creation of insanitary conditions.

*G. Shipping:*

- Prior to loading with foods, inspect rail car and truck and trailer interiors for general cleanliness and for freedom from moisture; from foreign materials which would cause product contamination (such as broken glass, oil, toxic chemicals, etc.) or damage to packaging and contents (such as boards, nails, harmful protrusions, etc.); and from wall, floor, or ceiling defects that could contribute to insanitary conditions.

- Clean, repair, or reject them as necessary to protect foods before loading.

- Exercise care in loading foods to avoid spillage or damage to packaging and contents.

- Maintain docks, rail sidings, truck bays, and driveways free from accumulations of debris and spillage.

*H. Warehouse Temperatures:*

- Maintain warehouse temperatures (particularly for refrigerated and frozen food storage areas) which are in compliance with applicable governmental temperature requirements, if any, for maintaining the wholesomeness of the particular foods received and held in such areas.

*I. Housekeeping, Sanitation and Inspection:*

- Establish a regularly scheduled program of general housekeeping, sanitation, and inspection to maintain floors, walls, fixtures, equipment, and other physical facilities in a state of sanitation sufficient to protect foods from contamination or adulteration, and to prevent waste from becoming an attractant and harborage or breeding place for vermin.

- In addition, develop and implement an effective program and procedure for timely cleanup of any debris and spillage resulting from accidents or other unscheduled occurrences.

#### *J. Pest Control Measures:*

- Implement pest control measures designed to prevent the entrance of pests, to deny them harborage, and to detect and eliminate them, with such schedules, instructions, and procedures, and by such trained and qualified personnel or professional representatives as may be necessary, based on the nature of the foods and other products handled, the structure and condition of the building and equipment, and the surroundings and environment of the warehouse.

- Monitor traps and bait stations, whether inside or outside of buildings, on a regular basis. Use covered interior bait stations designed, located, or protected to prevent spillage. Where appropriate, use bait stations constructed of moistureproof material.

#### *K. Pesticides:*

- Use only pesticides with labels showing USDA or EPA registration numbers, and only for the uses specified in the labeling.

- Have them applied only by responsible personnel in accordance with the manufacturer's labeling instructions and in a manner which prevents contamination of foods. While not in use, clearly mark and store pesticides in a secure place apart from foods.

#### *L. Audit Food Warehouse Sanitation Programs:*

- Establish programs internally and/or through outside consultants for effectively auditing the food warehouse sanitation program.

### **VII. PERSONNEL**

#### *A. Employee Practices:*

- Prohibit employees affected by disease in a communicable form, while carriers of such disease, or while afflicted with boils, sores, infected wounds, or other abnormal

sources of bacterial infection, from working in the food warehouse in capacities in which there is a likelihood of food becoming contaminated, or of disease being transmitted to other persons.

- Prohibit clothing or other personal belongings from being stored and food and beverages from being consumed and tobacco from being used in areas where foods are handled or stored.

- Instruct employees who are working in direct contact with exposed or partially exposed foods, such as produce items in mesh bags, etc., to maintain personal cleanliness and to conform to hygienic practices to avoid contamination of such foods with microorganisms or foreign substances such as human hair, perspiration, cosmetics, tobacco, chemicals, and medicants and, if gloves are used in handling such foods, to use only gloves which are of an impermeable material in handling such foods, and to maintain them in a clean and sanitary condition.

#### *B. Management Responsibilities:*

- Assign responsibility for the overall food warehouse sanitation program and authority commensurate with this responsibility to persons who, by education, training, and/or experience are able to identify sanitation risks and failures and food contamination hazards.

- Instruct employees in the sanitation and hygienic practices appropriate to their duties and the locations of their work assignments within the food warehouse. Instruct employees to report observations of infestations (such as evidence of rodents, insects or harborages) or construction defects permitting entry or harborage of pests, or other developments of insanitary conditions.

- Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.



## APPENDIX

This appendix to the Voluntary Industry Sanitation Guidelines for Food Distribution Centers and Warehouses has been prepared to assist the food warehouse operator in implementation of Sections (I) through (VII) of the *Guidelines*. Information in this appendix will require adaptation for specific application to your operations.

Since no single document can provide all the information necessary for every situation or specify the only methods for compliance, develop your own appendix or company guidelines to reflect your individual applications in the general areas dealt with in the *Guidelines* and this appendix.

### I. FOREWORD

To ensure product wholesomeness and proper sanitation, the food warehouse sanitation program must have the commitment of top management, must be implemented by operating supervision, and must be supported by the entire food warehouse staff. Preventive sanitation—the performance of inspection, sanitation, building maintenance, and pest control functions designed to prevent insanitation in preference to correcting it—should be an important goal of food warehouse management and of food warehouse operations.

### II. ORGANIZATION AND PROGRAMS

A program to ensure continued success in safeguarding the wholesomeness of food and in providing good sanitation will ordinarily include:

1. An organizational chart showing chain of authority and responsibility.
2. A flow diagram of receiving, storage, and shipping operations.



3. Regular maintenance schedules.
4. Regular sanitation programs.
5. Regular pest control programs.
6. An effective program of follow-up and control including reports to responsible executive officer(s).

### III. CHECK POINTS AND ADDITIONAL GUIDES

#### 1. *Grounds:*

- Keep nearby grounds free of liquid or solid emissions that could be sources of contamination.
- Prevent grounds from providing conditions for insect or rodent harborage.
- Check paving, drainage, weed, and litter control regularly.
- Stack materials which are stored in the open neatly and away from buildings, and on racks above ground level where feasible.
- "No-vegetation strips" around exterior building walls and at property lines adjacent to properties containing potential harborages are helpful for discovering and discouraging travel by rodents.

#### 2. *Buildings:*

- Provide separate and sufficient space for placement of equipment and storage of materials necessary for proper operations.
- Separate activities that might cause contamination of stored foods with chemicals, filth, or other harmful material.
- Check structural conditions, pest barriers, repair of windows, screens, and doors continuously.

- Seal and clean floor wall junctions and fill holes and cracks; a painted inspection strip is also recommended.

- Keep offices—including overhead offices—in the food warehouse clean, and do not permit them to become attractants or harborage for insects or vermin. Include them in the pest control program.

- Check false ceilings for harborage of insects and possibly rodents.

- Give basements, attics, elevators, and rail sidings, etc., special attention.

### 3. *Sanitary Operations:*

- Keep walls, ceilings and rafters free of soil, insect webbing, mold, and similar materials.

- Do not leave unscreened doors and windows open unnecessarily.

- Do not permit dust to accumulate.

- Keep floors free of product spillage, oil drippage, and buildup in all areas.

- Provide proper trash and refuse storage and removal.

- Store tools and equipment properly.

- Clean and flush drains regularly.

- Maintain railroad and truck courts free of debris, and properly patrol them for pest control.

- Keep eating and break areas, locker rooms, etc. clean and orderly. Vending machines are often overlooked: keep them and the areas adjacent to them clean and sanitary. Maintain equipment in a properly functioning condition and do not permit it to serve as a source of sanitation or harborage problems.

#### 4. *Receiving and Inspection:*

- Inspect the materials which are being received for evidence of damage; insect, bird, rodent, or other vermin infestation; and moisture, odor, or chemical contamination.
- Exclude contaminated materials, including product, pallets, and slip sheets, from the building.
- If damaged merchandise is accepted, segregate it for special handling.
- Make sure that incoming and outgoing vehicles are free of conditions that could contaminate product—no birds, rodents, insects, spillage, or objectionable odor should be evident.
- Code or mark foods received at the receiving point to ensure proper stock rotation.
- To facilitate handling of rejected and suspect product, it is often a good idea to develop procedures with individual shippers, carriers, and/or manufacturers for re-inspections, returns, etc.

#### 5. *Storage:*

- Store products in an orderly manner and so that date codes are visible for proper rotation.
- Generally, it is desirable to stack foods on pallets or racks (or on slip sheets, where a clamp truck operation is utilized), and away from walls so as to allow for inspection aisles between stacks and walls. Painting inspection aisles in a light color is often helpful in maintaining their effectiveness. Where full inspection aisles are not provided, take special care (such as more frequent inspection, rotation, and removal of product for cleaning) to ensure sanitary, pest free conditions.
- Separate bagged and baled foods to provide visibility between stacks.

- Dispose of contaminated or infested merchandise, or otherwise remove it from the food warehouse promptly.

- Promptly remove damaged merchandise and broken containers from general food storage areas. Handle and process salvageable merchandise separately in an area isolated from general food storage; this area probably will require extra sanitation and pest control attention.

- If salvage operations include the repackaging or other manipulation of exposed foods (other than items such as fresh produce received unpackaged or in partially open packages), conduct such operations in compliance with the food sanitation practices, guidelines, or regulations, such as 21 CFR 128, which are applicable to handling exposed foods.

- Do not intermingle chemicals, including pesticides, with food or food products. Such products are best separated by an aisleway.

#### **6. Pest Control:**

- Maintain written schedules, log activity, and monitor traps and bait stations regularly.

- Use covered bait stations which are of such types and so located as to reduce the danger of spoilage; and where appropriate, use moisture-proof bait stations.

- Keep the pesticides which are used in the food warehouse securely, and separate from foods. Permit their use only by properly trained personnel. Use only types registered and approved by an appropriate government agency for the intended use.

- Check especially for:

- rodent burrows in nearby grounds,

- activity at floor wall junctions and doorways, and

- insect crawl marks in dust accumulation, especially on overhead pipes, beams, window sills, around flour, sugar, and pet food storage.
- Where feasible, seal load levelers at docks to prevent trash accumulations and rodent harborage and entry; and clean them frequently.
- Look for insect activity in folds of bagged foods.
- Use black light, supplemented with means for distinguishing other chemicals that fluoresce, to check for rodent urine stains; and use flashlights to check for other evidence of contamination.

#### *7. Shipping:*

- Make sure that transportation equipment into which food warehouse food is loaded is maintained in a sanitary condition comparable to that of the food warehouse.
- Make sure that rail cars, trailers and trucks . . . are free of birds, rodents and insects or contamination from them,
  - . . . are free of odors, nails, splinters, oil, and grease,
  - . . . are free of accumulations of dirt or dunnage, and
  - . . . are in good repair and have no holes, cracks, or crevices that could provide entrances or harborages for pests.

#### *8. Follow-Up:*

8 Exercise programs of follow-up and control to ensure that your employees, consultants, and outside services are doing their jobs effectively.

## REPRINT OF PART 128, TITLE 21 OF FEDERAL REGULATIONS

PART 128—HUMAN FOODS; CURRENT GOOD MANUFACTURING  
PRACTICE (SANITATION) IN MANUFACTURE, PROCESSING,  
OR HOLDING

## Sec.

- 128.1 Definitions.
- 128.2 Current good manufacturing practice (sanitation).
- 128.3 Plant and grounds.
- 128.4 Equipment and utensils.
- 128.5 Sanitary facilities and controls.
- 128.6 Sanitary operations.
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- 128.8 Personnel.
- 128.9 Exclusions.
- 128.10 Natural or unavoidable defects in food for human use that present no health hazard.

**AUTHORITY:** The provisions of this Part 128 issued under secs. 402(a)(4), 701(a), 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4), 371(a) unless otherwise noted.

**SOURCE:** The provisions of this Part 128 appear at 34 FR 6977, Apr. 26, 1969, unless otherwise noted.

**§ 128.1 Definitions.**

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) "Plant" means the building or buildings or parts thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of human food.

(c) "Sanitize" means adequate treatment of surfaces by a process that is effective in destroying vegetative cells of pathogenic bacteria and in substantially reducing other micro-organisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

**§ 128.2 Current good manufacturing practice (sanitation).**

The criteria in §§ 128.3 through 128.8 shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

**§ 128.3 Plant and grounds.**

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(1) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests.

(2) Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.

(3) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or micro-organisms.

If the plant grounds are bordered by grounds not under the operator's control of the kind described in subpara-



graphs (1) through (3) of this paragraph, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be adequately cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes shall not be so suspended over working areas that drip or condensate may contaminate foods, raw materials, or food-contact surfaces. Aisles or working spaces between equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food-contact surfaces with clothing or personal contact.

(2) Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable microorganisms, chemicals, filth, or other extraneous material.

(3) Provide adequate lighting to hand-washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.



(4) Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.

(5) Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents)

#### § 128.4 Equipment and utensils.

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.*

Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, incidents

have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not include PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately de-

terminated so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

[38 FR 18012, July 6, 1973]

#### § 128.5 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts foods or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment utensils, or containers, or employee sanitary facilities require.

(b) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(c) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment or utensils or create an insanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. Toilet rooms shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using toilet.

(e) *Hand-washing facilities.* Adequate and convenient facilities for hand washing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an

attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies.

#### § 128.6 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

(b) *Animal and vermin control.* No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

(c) *Sanitation of equipment and utensils.* All utensils and product-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonproduct-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to minimize accumulation of

dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) should be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food or food-contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

(d) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment and utensils with product-contact surfaces should be stored in such a location and manner that product-contact surfaces are protected from splash, dust, and other contamination.

#### **§ 128.7 Processes and controls.**

All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that produc-



tion procedures do not contribute contamination such as filth, harmful chemicals, undesirable micro-organisms, or any other objectionable material to the processed product:

(a) Raw material and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into human food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of adequate quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

(b) Containers and carriers of raw ingredients should be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.

(c) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with adequate standards and stored, transported, and handled in a sanitary manner.

(d) Food-processing areas and equipment used for processing human food should not be used to process non-human food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.

(e) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(f) All food processing, including packaging and storage, should be conducted under such conditions and controls as are necessary to minimize the potential for unde-

sirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of the processed products.

(g) Chemical, microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be properly accomplished.

(h) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products, shall conform to any applicable food additive regulation (Part 121 of this chapter), and should provide adequate protection from contamination.

(i) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than 2 years.

(j) Storage and transportation of finished products should be under such conditions as will prevent contamination, including development of pathogenic or toxigenic micro-organisms, and will protect against undesirable deterioration of the product and the container.



**§ 128.8 Personnel.**

The plant management shall take all reasonable measures and precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable micro-organism) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, headbands, caps, or other effective hair restraints.

(6) Not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in

areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with micro-organisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education, or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this Part 128 shall be clearly assigned to competent supervisory personnel.

#### **§ 128.9 Exclusions.**

The following operations are excluded from coverage under these general regulations, however, the Commissioner will issue special regulations when he believes it necessary to cover these excluded operations: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

#### **§ 128.10 Natural or unavoidable defects in food for human use that present no health hazard.**

(a) Some foods, even when produced under current good manufacturing and/or processing practices, contain natural or unavoidable defects at lower levels that are not

hazardous to health. The Food and Drug Administration establishes maximum levels for such defects in foods produced under good manufacturing and/or processing practices and uses these levels for recommending regulatory actions.

(b) Defect action levels are established for products whenever it is necessary and feasible. Such levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse failure to observe either the requirement in section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food unlawful regardless of the defect level of the final food.

(e) Current action levels for natural and unavoidable defects in food for human use that present no health hazard are as follows. (Levels that have been adopted on a temporary basis prior to publication as a regulation may be obtained upon request at the Office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Room 15B-42, 5600 Fishers Lane, Rockville, Md. 20852.)